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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/430,177	10/29/99	NARANG	U 100448.01

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HM12/0406

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EXAMINER

WARE, T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/06/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/430,177

Applicant(s)

NARANG ET AL.

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-144 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-144 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 5, 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Receipt of declaration and IDS both filed 1-31-00, information disclosure statements filed 5-1-00 and 7-25-00, response to restriction requirement filed 1-24-01 and change of address filed 2-9-01 is acknowledged. Based upon applicants' response, the restriction requirement of 1-3-01 is withdrawn.

Claim Objections

1. Claims 125 and 144 are objected to because of the following informalities:
"sealable" appears to be mis-spelled as "saleable." Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6, 40, and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 40, and 82 claim antibiotics, antimicrobials, antiseptics, bacteriocins, bacteriostats, disinfectants and antibacterials. These claims are indefinite as these species appear to be the same as they are synonyms for antimicrobial agents. Correction is requested.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1615

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6, 10-13, 15-17, 20-23, 25-30, 33-36, 38-40, 43-44, 52-55, 62-82, 97-122, 135-137, and 141-143 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Clark et al (WO 97/31598; hereafter '598).

'598 discloses the same methods of making applicator tips and applicators as the instant claims (abstract; page 17, line 25-page 22, line 15; examples; claims). The applicators and applicator tips of '598 comprise antibacterial agents and the applicators have a conduit for an adhesive composition where the composition may flow through the applicator to the applicator tip. The tips are porous and may be made of foam in a variety of shapes.

6. Claims 1-4, 6, 10-13, 15-17, 20-23, 25-30, 33-36, 38-40, 43-44, 52-55, 62-82, 97-122, 135-137, and 141-143 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Leung (WO 96/40797; hereafter '797).

'797 discloses the same methods of making applicator tips and applicators as the instant claims (abstract; page 13, line 17-page 20, line 34; examples; claims). The applicators and applicator tips of '797 comprise antibacterial agents and the applicators have a conduit for an adhesive composition where the composition may flow through the applicator to the applicator tip. The tips are porous and may be made of foam in a variety of shapes.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 5, 7-9, 14, 18-19, 24, 31-32, 37, 41-42, 45--51, 56-61, 83-96, 123-134, 138-140, and 144 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (WO 97/31598; hereafter '598) or Leung (WO 96/40797; hereafter '797).

'598 and '797 teach substantially the same methods of making applicator tips and applicators as the instant claims. The applicators and applicator tips of '598 and '797 comprise antibacterial agents and the applicators have a conduit for an adhesive composition where the composition may flow through the applicator to the applicator tip. The tips are porous and may be made of foam in a variety of shapes. Neither '598 nor '797 teaches the specific antimicrobial agents of the instant claims, however it is submitted that these agents are known antimicrobial agents and based upon the inclusion of antimicrobial agents in '598 and '797 it would have been obvious to one skilled in the art at the time of the invention to include the specific antimicrobial agents, absent a demonstration of criticality thereto.

'598 and '797 also do not teach forming a concentration gradient of the agent, however it would have been obvious to one skilled in the art at the time of the invention to utilize a concentration gradient to allow the agent to flow from the conduit to the applicator tip.

'598 and '797 also do not teach kits comprising sealable packages comprising the applicators and applicator tips, however they do teach separate storage within an applicator container. Sealability of these would have been obvious to one skilled in the art at the time of the invention to permit re-use of the applicators while minimizing exposure to environment, subsequent exposure to micro-organisms and degradation of the active agent.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 25, 67-102, 125-134 and 144 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of copending Application No. 09/430,176. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of delivering the agent of 09/430,176 discloses the applicators of the instant claims.

Art Unit: 1615

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

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April 2, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER/1600